Remarks/Arguments

Claims 1, 6-9, 11, 15-17 and 21-34 remain in this application. Applicant acknowledges the withdrawal of the objection to the specification, the withdrawal of the rejection of Claims 1, 6-9, 11, 15-17 and 21-34 under 35 U.S.C. §112, 1st paragraph and the allowance of Claims 1, 6-9, 11, 15, 16, 22, 24-29, 31, 32 and 34.

Claim rejections- 35 U.S.C. §103(a)

Claims 17, 21, 23, 30 and 33 are rejected under 35 U.S.C. §103(a) as being unpatentable over Japanese Patent No. 03197421 to Hirashima. The Office Action asserts that Hirashima teaches a controlled release tablet coated with 12g of ethyl cellulose and 8g PEG (40%). The Office Action further asserts that the tablet comprises total active that falls within the 5-95% active required for the tablet of the instant claims and that the coat comprising 12 g ethyl cellulose falls within the range of about 5 to less than 50% by weight of polymer in the coat. The Office Action admits that Hirashima does not teach that the coating is non-permeable and soluble in a pH of above about 5. The Office Action asserts, however, that one skilled in the art would have expected the coat of Hirashima to be non-permeable and soluble in a pH of above about 5 since the coat of Hirashima comprises %PEG and %polymer that falls within the ranges of the instant claims. Applicant respectfully disagrees.

With respect to independent Claims 17, 23 and 33, these claims are directed to an extended release pharmaceutical active formulation comprising an encasement coat being non-permeable and soluble in a pH of above about 5.0 and comprising about 5 to less than 50% by weight of polymer. The coat of Hirashima may comprise 12 g of ethyl cellulose but it does not fall within the range of about 5 to less than 50% by weight of polymer in the coat. 12 g of ethyl cellulose and 8 g of polyethylene glycol corresponds to 60% ethyl cellulose and 40% polyethylene glycol, respectively. The percentage of ethyl cellulose, 60%, is a percentage that clearly does not fall within the claimed ranges. In addition, it is submitted that it would not be obvious to one of skill in the art to conclude that the coat of Hirashima would be non-permeable and soluble in a pH of above about 5.0. To establish *prima facie* obviousness of a rejected claim,

the applied art of record must teach or suggest each and every feature of a rejected claim. See M.P.E.P. §2143.03. Hirashima does not teach or suggest these properties of the coat or the specific percentage(s). In fact, the coat of Hirashima would be permeable. The polyethylene glycol of the coat of Hirashima would dissolve in solution producing porous channels in the coat, while maintaining its' integrity even after the active had leached out. The coat of Hirashima would not be soluble at any pH. In contrast, the coat of the claimed invention is non-permeable and soluble in a pH of above about 5.0.

In addition, with respect to Claims 17 and 23, Hirashima does not teach or suggest the inclusion of about 0.5%-30% by weight polyethylene glycol or 0.5%-30% by weight plasticizer comprising polyethylene glycol, respectively, in the coat. The polyethylene glycol of Hirashima is outside the ranges of the components of the claimed invention.

For these reasons, it is respectfully submitted that independent Claims 17, 23 and 33 are patentable over Hirashima and consequently, Claims 21 and 30, which are dependent, or ultimately dependent, from Claim 17, are also patentable over Hirashima.

Conclusion

In view of the foregoing, reconsideration of the application, withdrawal of the outstanding rejections, allowance of Claims 1, 6-9, 11, 15-17 and 21-34, and the prompt issuance of a Notice of Allowability are respectfully solicited.

In the event that this paper is not considered to be timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fees for such an extension, together with any additional fees that may be due with respect to this paper, may be charged to Sim & McBurney's Account No. 192253, referencing docket number 9577-25 LAB.

Respectfully submitted,
SIM & McBURNEY

By _____
Lola A. Bartoszewicz, PhD.
Reg. No. 43,394
Tel.: (416) 595-1155